

I. AMENDMENTS

AMENDMENTS TO THE CLAIMS

Please enter the amendments to claims 1-4, 8, 9, 25, 29-34, 38, and 39, as shown below.

Please enter new claims 40-48, as shown below.

1. (Currently amended) A solid formulation comprising at least one antibody, and histidine in a concentration of from greater than 20 mM to about 60 mM a sufficient amount to stabilize said at least one antibody in said solid formulation.

2. (Currently amended) The solid formulation of Claim 1, further comprising [[an]] at least one additional excipient.

3. (Currently amended) The solid formulation of Claim 2, wherein said at least one [[other]] additional excipient is selected from the group consisting of: mannitol, Polysorbate 20, Polysorbate 80, succinate, citrate, Tris, phosphate, sucrose, trehalose, amino acids, polyols, Polyethylene glycol [[PEG]], bovine serum albumin [[BSA]], sucrose, lactose, maltose, and sorbital.

4. (Currently amended) The solid formulation of Claim 2, wherein said at least one [[other]] additional excipient is arginine.

5. (Original) The solid formulation of Claim 1, wherein said at least one antibody is a mammalian antibody.

6. (Original) The solid formulation of Claim 1, wherein said at least one antibody is a human antibody.

7. (Original) The solid formulation of Claim 1, wherein said at least one antibody is a human monoclonal IgG₂ antibody.

8. (Currently amended) The formulation of Claim 1, wherein the sufficient amount of histidine is present in a concentration of from greater than 20 mM to about between 6 and 40 mM.

9. (Currently amended) The formulation of Claim 1, wherein the ~~sufficient amount of histidine is present in a concentration of about 40 mM~~ ~~15 mM~~ of histidine.

10. (Withdrawn) A method of preparing an antibody in a solid formulation comprising: mixing at least one antibody with a stabilizing amount of histidine to form a mixture; and treating said mixture to generate a solid formulation of said antibody and said histidine.

11. (Withdrawn) The method of Claim 10, wherein treating said mixture comprises lyophilizing said mixture.

12. (Withdrawn) The method of Claim 10, wherein said solid formulation is a lyophilized cake.

13. (Withdrawn) The method of Claim 11, wherein lyophilizing said mixture comprises: freezing said mixture at a rate of about -0.35°C per minute until said mixture reaches a temperature of about -45°C ; and
sufficiently drying said mixture.

14. (Withdrawn) The method of Claim 13, wherein drying comprises a primary and a secondary drying.

15. (Withdrawn) The method of Claim 12, further comprising reconstituting said lyophilized cake with a reconstituting agent.

16. (Withdrawn) The method of Claim 15, wherein said reconstituting agent comprises water for injection (WFI).

17. (Withdrawn) The method of Claim 10, further comprising adding at least one other excipient to said mixture.

18. (Withdrawn) The method of Claim 17, wherein said at least one other excipient is selected from the group consisting of: mannitol, Polysorbate 20, Polysorbate 80, succinate, citrate, Tris, phosphate, trehalose, amino acids, polyols, PEG, BSA, sucrose, lactose, maltose, and sorbital.

19. (Withdrawn) The method of Claim 15, wherein said at least one other excipient is arginine.

20. (Withdrawn) The method of Claim 10, wherein the stabilizing amount of histidine is between 6-40 mM.

21. (Withdrawn) The method of Claim 10, wherein the stabilizing amount of histidine is about 15 mM.

22. (Withdrawn) The method of Claim 11, wherein lyophilizing said mixture occurs in less than 100 hours.

23. (Withdrawn) The method of Claim 11, wherein lyophilizing said mixture occurs in less than 50 hours.

24. (Withdrawn) The method of Claim 11, wherein lyophilizing said mixture occurs in about 45 hours.

25. (Currently amended) A kit for preparing a solid formulation of a stabilized antibody comprising;

a first container, comprising at least one antibody in solution, and
a second container comprising a sufficient amount of histidine in solution to stabilize said antibody when said antibody is dried into a solid formulation, such that the concentration of histidine in the solid formulation is from greater than 20 mM to about 60 mM.

26. (Original) The kit of Claim 25, wherein said antibody is a mammalian antibody.

27. (Original) The kit of Claim 25, wherein said antibody is a human antibody.

28. (Original) The kit of Claim 25, wherein said antibody is a human monoclonal IgG₂ antibody.

29. (Currently amended) The kit of Claim 25, wherein the sufficient amount of histidine is such that the concentration of histidine in the solid formulation is from greater than 20 mM to about 40 mM between 6-40 mM.

30. (Currently amended) The kit of Claim 25, wherein the sufficient amount of histidine is such that the concentration of histidine in the solid formulation is about 40 mM ± 15 mM.

31. (Currently amended) A liquid formulation comprising at least one antibody, and histidine in a concentration of from greater than 20 mM to about 60 mM a sufficient amount to stabilize said at least one antibody in said liquid formulation.

32. (Currently amended) The liquid formulation of Claim 31, further comprising [[an]] at least one additional excipient.

33. (Currently amended) The liquid formulation of Claim 32, wherein said at least one [[other]] additional excipient is selected from the group consisting of: mannitol, Polysorbate 20, Polysorbate 80, succinate, citrate, Tris, phosphate, sucrose, trehalose, amino acids, polyols, polyethylene glycol [[PEG]], bovine serum albumin [[BSA]], sucrose, lactose, maltose, and sorbital.

34. (Currently amended) The liquid formulation of Claim 32, wherein said at least one other additional excipient is arginine.

35. (Original) The liquid formulation of Claim 31, wherein said at least one antibody is a mammalian antibody.

36. (Original) The liquid formulation of Claim 31, wherein said at least one antibody is a human antibody.

37. (Original) The liquid formulation of Claim 31, wherein said at least one antibody is a human monoclonal IgG₂ antibody.

38. (Currently amended) The liquid formulation of Claim 31, wherein the ~~sufficient amount of~~ histidine is present in a concentration of from greater than 20 mM to about between 6 and 40 mM.

39. (Currently amended) The formulation of Claim 31, wherein the ~~sufficient amount of~~ histidine is present in a concentration of about 40 mM 15 mM of histidine.

40. (New) The solid formulation of claim 1, wherein said antibody is a recombinant antibody.

41. (New) The solid formulation of claim 1, wherein said antibody is an immunospecific antibody fragment.

42. (New) The solid formulation of claim 1, wherein said antibody is present in a concentration of from about 5 mg/mL to about 100 mg/mL.

43. (New) The kit of claim 25, wherein said antibody is a recombinant antibody.

44. (New) The kit of claim 25, wherein said antibody is an immunospecific antibody fragment.

45. (New) The kit of claim 25, wherein said antibody is present in a concentration of from about 5 mg/mL to about 100 mg/mL.

46. (New) The liquid formulation of claim 31, wherein said antibody is a recombinant antibody.

47. (New) The liquid formulation of claim 31, wherein said antibody is an immunospecific antibody fragment.

48. (New) The liquid formulation of claim 31, wherein said antibody is present in a concentration of from about 5 mg/mL to about 100 mg/mL.